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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,233	10/21/2003	Stefan A. Sharpe	PD01642	4939

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
BETTON, TIMOTHY E	
ART UNIT	**PAPER NUMBER**
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,233	SHARPE ET AL.	
	Examiner	Art Unit	
	Timothy E. Betton	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6, 8, 10,11, and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 8,10,11, and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date [illegible].
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of species election in the reply filed on 6 November 2006 is acknowledged. The traversal is on the ground(s) that Applicants submit that it would not be an unduly burdensome search on the part of the Examiner. As a result, applicant has allegedly amended the claims and canceled claims without prejudice so that said response is responsive to the Office Action.

Instant claims 1-6, 8, 10,11, and 14 are pending for prosecution on the merits.

Claim Rejections 35 U.S.C.§ 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8, 10,11, and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for assessing methods of determining a secondary structure of a thixotropic formulation, said method comprising a) placing an amount of said thixotropic formulation on a transparent object; b) capturing an image of said thixotropic formulation by back-scattered light by using a particle vision and measurement probe; c) converting said image to a video image; d) analyzing said video image to determine the amount of time it takes for the formation of said secondary structure within said thixotropic formulation. However, the specification does not reasonably provide enablement for actual intranasal administration to human subject to properly assess claimed invention. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

As stated in MPEP 2164.01(a), " There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue."

In re Wands , set forth the following eight factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, 1ST paragraph:

1. The nature of the invention;
2. The state of the prior art;
3. The predictability or lack thereof in the art;
4. The amount of direction or guidance present;
5. The presence or absence of working examples;
6. The breadth of the claims;
7. The quantity of experimentation needed; and
8. The level of the skill in the art.

The nature of the invention

The nature of the invention presents complex issues in regard to nasal administration commensurate in scope of enablement of claimed invention.

The state of the prior art and the predictability or lack thereof in the art

There is no absolute predictability even in view of the seemingly high level of skill in the art. For exemplary purposes, Sharpe et al. (PG PUB US 2004/0081625 A1) discloses: A common problem with spray administration is that the structure of body cavities and parts does not typically facilitate retention of the applied formulation. This is particularly the case for aqueous-based nasal spray formulations, which must have sufficient fluidity to be dispensed by a pump device or a squeeze-type spray bottle, but which can simply

drain from the nose or pass through the nose and into the pharynx while, or immediately after, being sprayed. Moreover, due to ciliation of the nasal passages and movement of air through the nose, even materials applied in particulate form, such as by a pressurized metered dose inhaler or a powdered drug inhaler, are rapidly cleared from the nose. Several of the possible active agents or other formulation components have a quite unpleasant taste, so it is desirable to minimize the amount of the formulation which is not retained within the nose for at least the minimum time required to obtain the desired effect. Due to swallowing of much of the formulation, which enters the oropharyngeal area, a large portion of the active agent introduced into the nose is generally rendered unavailable for its intended use (page 1, section [0007]).

The amount of direction or guidance present and presence or absence of working examples

There is referenced direction or guidance in Applicants' specification for a method of determining secondary structure of a thixotropic formulation. Instant claim 2 suggests that method is ultimately directed toward intranasal administration to a human subject. However, instant specification discloses only a general explanation of common problems associated with actual intranasal administration to a human subject. Working examples elucidating methods of determining secondary structure on a human subject is absent.

The breadth of the claims, quantity of experimentation, and level of skill in the art

Those of skill in the art recognize that in vitro studies, i.e., determining thixotropic formation on a transparent object is generally useful to observe basic yield stress, viscosity, and thixotropy. However, clinical comparison is lacking. The greatly increased complexity of the *in vivo* environment as compared to the very narrowly defined and controlled conditions of a method of determining thixotropic formation on transparent plate may not accurately translate to human diagnostic efficacy with any reasonable degree of predictability.

In view of the teachings above and the lack of guidance, workable examples and/ or exemplification in the specification, it would require undue experimentation by one of skill in the art to determine with any predictability, that the method would function as claimed.

Claim Rejections 35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8, 10,11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over TA Instruments (PN 500017.002 Rev.B, AR500/1000 Rheometers

Hardware Manual (2000), TA Instruments Thermal analysis and Rheology, pps 1-104, 1-1 to 1-10) and Penkethman (USPN 5,450,203), in view of Ward et al. (PG PUB US 2002/0112836 A1).

TA Instruments (Rheometers Hardware Manual) teach the exact method of determining the magnitude of thixotropy. Instant specification discloses geometry, i.e., measurement parameters that are properly encompassed by TA Instruments (Rheometers Hardware Manual). Measuring Systems in referenced chapter 6 teach " Choosing the Best Geometry" for cones and plate/ parallel plate systems covering the particulars when adjusting for certain angles and diameter. Accordingly, on page 6-12, it specifically teaches on the cone and plate and parallel plate systems requiring small sample volumes to achieve a uniform shear rate of sample. This is obvious over applicants claim in instant specification that this is the central inventive issue of subject claims. Reference Chapter 7 teaches AR Rheometer Enhancements and Options and in Chapter 8 teaches the method of attaching geometry in order to properly adjust for any sample.

TA Instruments (Rheometers Hardware Manual) does not teach the capturing of image by back-scattered light by a particle and vision measurement probe, the converting of image to video image and/or the analysis thereof.

Penkethmen teaches light supplied via optical fiber to a probe head. The light exiting the optical fiber is focused to a point by a lens. Reflected light from an object at or near the focal point is reflected back through the lens and then focused to the source optical fiber or a second optical fiber located next the source optical fiber. The return

signal is then detected in a detector module. By noting the characteristics of the response curve as the object is moved back and forth relative to the probe head, the position of the object can be determined. By performing this procedure over several points, a detailed topography map can be created. Additionally, the probe head can be scanned at a constant distance from the surface to produce an image of the surface as the response signal varies according to the surface's reflectivity. The microprobe can be used, for example, to find the position of probe tips on a wafer prober, to determine the topography of the surface of the wafer, and to find the position of the wafer edge (Abstract). Penkethmen, therefore, depicts basic steps of a method of determining thixotropic properties of formulations.

Penkethman does not teach specifically on Rheology or thixotropy. However, the Examiner refers to Ward et al., which teach a structurally rigid polymeric coagulant and an effective flocculating amount of a flocculent and a microparticle. Accordingly, section ([0083], 1st paragraph) and ([0084], 2nd paragraph) of Penkethman are obvious over instant claim 1, specifically subset's b) through d), which teach the measurement of a sample via back-scattered light.

Therefore, it would be prima facie obvious to combine the teachings of TA Instruments and Penkethmen by way of the motivation of Ward et al. One of ordinary skill in the art would have instantly at the time of invention practiced a combination thereof or an incorporation together of TA Instruments (Rheometers Hardware Manual) and Penkethman in obviousness over applicant's claimed invention.

Applicant's central issues of invention, being a method of determining the magnitude of thixotropy via product AR1000 Rheometer and a method of determining a secondary structure of a thixotropic formulation via product Particle Vision and Measurement 700 probe is thereby overcome.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

Ardin H. Marschel 1/8/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER